DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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July 28, 2005

NOTE TO DOCKET NO. 2001N-0275

SUBJECT: Electronic Products; Performance Standard for Diagnostic X-Ray Systems and Their Major Components

PUBLICATION DATE: June 10, 2005

On September 30, 1993, President Clinton signed Executive Order 12866--Regulatory Planning and Review. This Executive Order sets forth the Administration's principles and requirements for the Federal regulatory process. Under section 6(a)(3)(E) of the Executive Order, for "significant regulatory actions," Federal agencies must make certain information available to the public after publication of the regulatory action in the Federal Register.

Pursuant to Executive Order 12866, FDA has attached, for the significant regulatory action in this docket, the following information:

1) A copy of the draft regulatory action as submitted to the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) for review including any materials or assessments, required by the Executive Order that accompanied the draft (Tab A);

2) The substantive changes between the draft submitted to OIRA for review and the action subsequently announced, including those changes in the regulatory action that were made at the suggestion or recommendation of OIRA (Tab B).

Nancy E. Pirt
Regulations, Policy,
and Management Staff (HF-26)

Attachments

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